

REMARKS

Claims 1 and 3-9 are pending in the instant application. Claims 1 and 3-9 stand rejected under 25 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by WO 95/27438 to Balamore. Claims 1 and 3-9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,210,976 to Sabbadini in view of Balamore. Claims 1, 3, and 4 have been amended. New claim 10 has been added. Applicants respectfully submit that none of the amendments constitute new matter in contravention of 35 U.S.C. §132. Reconsideration is respectfully requested.

Claims 1 and 3-9 stand rejected under 25 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully submit that each of the Examiner's rejections are obviated by the amendments to the claims.

Applicants respectfully point out that while the Examiner has rejected claim 1 for indefiniteness, the Examiner provided no explanation for the rejection. Nevertheless, Applicants respectfully submit that claim 1, as amended, should preclude any objections of indefiniteness.

Applicants further submit that the amendments to claims 3 and 4 preclude any objections of indefiniteness.

In view of the amendments to claims 1, 3, and 4, Applicants respectfully submit that claims 1 and 3-9 meet the requirements of 35 U.S.C. §112, second paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by WO 95/27438 to Balamore. This rejection is respectfully traversed.

Balamore is directed to imaging a biological structure, for example a lung.

The Examiner asserts that Balamore discloses an *in vitro* method comprising labeling a biological molecule with hyperpolarized Xe and observing an NMR spectrum of the hyperpolarized Xe. He further asserts that the biological molecule is an assay agent taking part in an assay method since "assay means an analysis".

However, in the specification on page 3, lines 1-2, the Applicants have made it clear that by "assay" it is meant a reaction of one or more biological molecules. Furthermore, this distinction is reflected in amended claim 1, which is now directed to an *in vitro* assay method which is a test involving a reaction of one or more biological molecules. Similarly, new claim 10 is directed to an *in vitro* assay method for following the progress of a reaction of one or more biological molecules. The method of Balamore is not an assay method as defined in amended claim 1 or in new claim 10 and it is clear that assay methods in this sense are not contemplated by Balamore.

Similarly, new claim 10 is patentably distinct over Balamore as it recites a process having the step of observing the change in the NMR spectrum with time over the course of the reaction. This is completely different from anything taught by Balamore, which relates to a method of taking static images of a biological system at a single time point.

Therefore, as Balamore fails to disclose, teach, or suggest the present invention, Applicants respectfully submit that claims 1 and 3 to 10 are patentably distinguishable over Balamore. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1 and 3-9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over United States Patent No. 6,210,976 to Sabbadini in view of Balamore. This rejection is respectfully traversed.

Sabbadini relates to a method of detecting heart disease comprising:

- a. measuring a level of a non-polypeptidic cardiac marker in the test sample from the mammal; and
- b. determining if the level of the cardiac marker measured in the test sample correlates with cardiac ischaemia or hypoxia.

The Examiner states that Sabbadini, in the first paragraph at column 4 and in the bridging paragraph of columns 6-7, discloses an *in vitro* method comprising observing an

NMR spectrum or image as the detection step in an immunoassay. However, Applicants respectfully submit that this is not the case. The passage to which the Examiner refers (column 4 lines 1-5) teaches that the measuring step comprises measuring the marker level by a method selected from the group consisting of chromatography, immunoassay, enzymatic assay and spectroscopy. Sabbadini then further states that one method of spectroscopy is NMR (column 4, lines 13-16). Thus, it is quite clear that Sabbadini considers immunoassay and spectroscopy to be **alternative and distinct** methods of measuring the marker level, not steps to be somehow combined. Thus, Sabbadini does **not** teach observing an NMR spectrum or image as the detection step in an immunoassay. The same deficiency exists in the cited passage bridging columns 6 and 7 as this passage also makes it clear that immunoassay, enzymatic assay and spectroscopy are alternative methods of measuring the level of cardiac marker.


Therefore, Sabbadini fails to disclose, teach, or suggest an assay method in which the reaction of a biological molecule is observed *via* the NMR spectrum of hyperpolarized ^{129}Xe with which the biological molecule is labeled. Moreover, Balamore fails to overcome these deficiencies in Sabbadini. As a result, Applicants respectfully submit that the amended claims are patentably distinguishable over Sabbadini in view of Balamore. Reconsideration and withdrawal of the rejection are respectfully requested.

In view of the amendments and remarks hereinabove, Applicants respectfully submit that the present application, including claims 1 and 3-10, are patentably distinct over the prior art. Favorable action thereon is respectfully requested.

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Any questions with respect to the foregoing may be directed to Applicants'
undersigned counsel at the telephone number below.

Respectfully submitted,



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